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Koppers Company, Inc.
440 College Park Dr.
Monroeville, PA 15146

September 8, 1981

Dr. John Hilcken, Director
Toxic Substances Information
Department of Health
Commonwealth of Virginia
Madison Building
109 Governor Street
Richmond, VA 23219

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ATTORNEY GENERAL

Dear Dr. Hilcken:

Enclosed is a final copy of the AWPI response to the nomination of creosote and coal tar for Class 1 Substances in the State of Virginia.

Please note that we would also like included in our formal submission the following two items, of which I believe you already have copies:

Response of the American Wood Preservers Institute to EPA'S
Position Document for Wood Preservative Pesticides: Creosote,
Coal Tar, and Coal Tar Neutral Oil - Vol. I through V,
February 12, 1979.

Response of the American Wood Preservers Institute to EPA'S
Position Document 2/3 for Wood Preservative Pesticides:
Creosote, Coal Tar, and Coal Tar Neutral Oil - Vol. I and II,
May 20, 1981.

If you should have any additional questions concerning our submission, please contact Mr. Walt Tararek, AWPI, McLean, VA. We appreciate the consideration your department has given in reviewing the information on creosote and coal tar.

Sincerely,

David A. Webb
Chairman
AWPI/EPTG No. 5

DAW/bjm
Enclosure

cc: Mr. W. G. Tararek

bcc: AWPI/EPTG No. 5 Members

PRESENTED TO
VIRGINIA DEPARTMENT OF HEALTH
RICHMOND, VIRGINIA

RESPONSE OF THE
AMERICAN WOOD PRESERVERS' INSTITUTE
TO THE NOMINATION OF
CREOSOTE AND COAL TAR FOR
DESIGNATION AS CLASS 1 SUBSTANCES

AMERICAN WOOD PRESERVERS' INSTITUTE
1651 OLD MEADOW ROAD
MCLEAN, VIRGINIA 22102

AUGUST 18, 1981

This paper has been prepared in response to the Virginia State Department of Health draft report, "Nomination of Creosote and Coal Tar for Designation as Class 1 Substances." As indicated by the report, the only reference source was the Environmental Protection Agency (EPA) Position Document 1, "Notice of Rebuttable Presumption Against Registration and Continued Registration of Pesticide Products Containing Coal Tar, Creosote, and Coal Tar Neutral Oil" as it appeared in the Federal Register Volume 43, No. 202, 48154-48266.

The State of Virginia's Department of Health has indicated an interest in reviewing additional data germane to the subject. The American Wood Preservers' Institute (AWPI) has transmitted to the Health Department a copy of the following papers:

- Response of the American Wood Preservers Institute to EPA's Position Document for Wood Preservative Pesticides: Creosote, Coal Tar, and Coal Tar Neutral Oil - Vol. I through V, Feb. 12, 1979
- Response of the American Wood Preservers' Institute to EPA's Position Document 2/3 for Wood Preservative Pesticides: Creosote, Coal Tar, and Coal Tar Neutral Oil - Vol. I and II, May 20, 1981

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U.S. DEPARTMENT OF JUSTICE

Creosote, Coal Tar and Coal Tar Neutral Oil⁽¹⁾ Have Not Been
Demonstrated to be Oncogenic

On the basis of certain studies, including experiments involving dermal application to or inhalation of creosote/coal tar by rodents, and reports of workers occupationally exposed to creosote/coal tar, PD 1 concluded that creosote/coal tar solutions are human oncogens.

AWPI's Rebuttal extensively documents the unreliability of EPA's grossly limited occupational exposure studies.⁽²⁾ In brief summary, those human reports relied upon by EPA have a limited and unreliable data base, are anecdotal in nature and devoid of adequate statistical analysis, do not account for changed occupational hygienic and safety practices that have occurred since the dates of the reports, lack detailed vocational and medical histories, ignore the other common causes of cancer, particularly skin and lung carcinomas, and are overwhelmingly rebutted by recent epidemiological and other health studies.

EPA, while recognizing the shortcomings of these case reports, adheres to its position in PD 2/3 that the reports support its concern for the long-term effects of exposure to creosote/coal tar. Indeed, the Agency continues to cite such questionable studies as the Shambaugh fishermen reports as evidence of the oncogenicity of creosote/coal tar,

(1) Creosote, coal tar, and coal tar neutral oil products used as wood preservatives will be referred to collectively herein as "creosote/coal tar."

(2) AWPI Rebuttal, Volume II: Lederer, 2-5; Leber, 2-14; Jones, 10-12, 26-29.

even though more modern studies categorically reject Shambaugh's conclusions: "More recently, Spitzer . . . has concluded on the basis of a more thorough study that far from being carcinogenic, the coal tar treated nets seemed to protect the fishermen from lip cancer, since those who used their mouths as 'third hands' were less than 50% as likely to contract lip cancer than those fishermen who repaired the nets using other techniques." (AWPI Rebuttal, Volume I, at 21; Volume II, Jones, 10-11; Lederer, 2-3; Wentzel, 12).

EPA states in PD 2/3 that it relies upon animal studies primarily because of the unavailability of adequate epidemiological studies, and states that the agency is unaware of any adequate long-term studies to characterize the oncogenic effects of the use of coal tar medicinals in the induction of skin cancer. Yet, such a study has recently been performed by the Mayo Clinic;⁽³⁾ and recent epidemiological studies by Lloyd and Redmond (q.v.), Reid and Buck (q.v.), and Doll (q.v.), demonstrate no increased incidence of skin or respiratory cancer associated with occupational exposure to coal tar distillates.⁽⁴⁾

(3). Volumes I and II of the AWPI Rebuttal refer to the Mayo Clinic's use of the so-called Goeckerman treatment and to the anecdotal observation that no skin cancers have been reported in current and former patients. Since the time of submission of the AWPI Rebuttal, however, the Mayo Clinic has performed a rigorous epidemiological follow-up study that is the subject of the discussion here. The results of the study are contained in two reports. The first report, dealing with atopic dermatitis patients

and entitled "Incidence of Skin Cancers in Patients With Atopic Dermatitis Treated with Coal Tar: A 25-year Follow-up Study," is published at Journal of the American Academy of Dermatology 3: 612-615 (1980). The second report, entitled "Incidence of Skin Cancers in Psoriatic Patients Treated with Coal Tar: A 25-year Follow-up Study," is currently unpublished. However, the results were reported to the Food and Drug Administration at the December 9, 1979 meeting of the FDA Miscellaneous External Drug Products Review Panel. A copy of the first report, and a summary and transcript of the December 9, 1979 meeting, are contained in Volume II, Section 2.

- (4) For a more thorough discussion of these studies, see Poel, Volume II, Section 1, at 2-13.

Nomination of Creosote and Coal Tar for Designation as Class 1

Substances

It is believed to be not appropriate at this time to make a decision concerning the health risk of creosote and coal tar. It has not been demonstrated that there is a hazard. In fact, recent epidemiological information on creosote workers in wood pressure treating plants indicates they do not have skin or any other kinds of cancer problems.

It is recognized that there are components in creosote and coal tar which have been shown to be carcinogens; however, many of the compounds suggested by draft document VTSIR-11 to be components of creosote/coal tar are for the most part minor components.

Lorenz and Gjovik⁽⁵⁾ analyzed 18 major components (i.e., greater than one percent) in a typical creosote as determined by a gas chromatographic technique (see attached Table I). The draft document VTSIR-11 lists 13 compounds known to be present in creosote/coal tar that have previously been recognized as cancer causing agents. Chrysene is the only compound which appears in both the list of compounds from Lorenz and Gjovik and the VTSIR-11 documents.

(5) Lorenz, L. F. and L. R. Gjovik. 1972. Analyzing Creosote by Gas Chromatography: Relationship to Creosote Specifications. Proceedings AWWA, Vol. 68, pp. 32-42

It is not proper to draw the conclusion that creosote/coal tar is a health risk when one or more of its major or minor components may have chronic toxicity. Under appropriate conditions, many common and, sometimes, naturally occurring substances have been shown to have carcinogenic potential in test animals. These include egg yolk and white, caffeine, calcium, beverage alcohol, lactose and maltose, selenium and Vitamin D. Also, peanuts and corn contain aflatoxin, which is a well known carcinogen.

It must also be considered that these are anti-carcinogenic compounds in creosote products. For example, Poel⁽⁶⁾ reported that applications of the acid fraction (phenols, etc.) had an appreciable tumor-retarding effect with the experimental carcinogen, 3,4-benzopyrene (BaP) on the skin of mice.

A further statement concerning BaP is warranted. BaP is a polynuclear aromatic hydrocarbon that is present in trace amounts in coal tar products. However, it should be considered that BaP is present in the combustion products of all organic matter. It is found in the air we breathe, in fires of all sorts (such as forest fires, meats we charcoal broil and eat, etc.) in the water we drink - - basically, BaP is ubiquitous.

(6) Poel, W. E., "Critical Review of the EPA Position Document No. 1 on Coal Tar, Creosote and Coal Tar Neutral Oil." AWPI Response to EPA (PD 1), Vol. II, Feb. 1979.

Conclusion





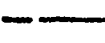



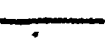







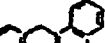

In conclusion, the carcinogenic effects in humans allegedly produced by coal tar/creosote cannot be considered valid scientific evidence. Today, the nature and causes, and treatment, of skin cancer are better understood. It has been shown that solar radiation (sunlight) is the most common cause of skin cancer and that, with prompt medical treatment, the cure rate can approach 100%. Also, conditions of manufacture and use of creosote in this country today differ from those reported in the early literature, and these early studies should not be considered representative of the industry as it presently exists.

AWPI maintains that animal studies are indeterminate at best, inapplicable to humans, and irrelevant when considering modern epidemiological evidence that creosote/coal tar are not occupational carcinogens.

With respect to exposure data, AWPI has presented a detailed analysis in the PD 2/3 paper. The current OSHA standard for CTPV is 0.2 mg/m³ as benzene soluble fraction. Exposure data indicates levels of worker exposure to be significantly below the 0.2 mg/m³ level.

TABLE I

MAJOR COMPONENTS IN CREOSOTE

Peak No.	Component	Whole Creosote	Boiling Point	Melting Point	Structural Formula	Molecular Weight
		Approx. Pct. $\pm 0.7\%$	$^{\circ}\text{C. } 760$	$^{\circ}\text{C.}$		
1	Naphthalene	3.0	218	80.55		128.2
2	2-Methylnaphthalene	1.2	241.05	24.58		142.2
3	1-Methylnaphthalene	.9	244.64	-22		142.2
4	Biphenyl	.8	255.9	71		154.2
5	Dimethylnaphthalenes	2.0	268	7.66, 105		156.2
6	Acenaphthene	9.0	279	96.2		156.2
7	Dibenzofuran	5.0	287	86-87		168.2
8	Fluorene	10.0	293-295	116-117		166.2
9	Methylfluorenes	3.0	318	46-47		180.2
10	Phenanthrene	21.0	340	101		178.2
11	Anthracene	2.0	340	216.2-.4		178.2
12	Carbazole	2.0	355	247-248		167.2
13	Methylphenanthrenes	3.0	354-355	65-123		192.2
14	Methylanthracenes	4.0	360	81.5-209.5		192.2
15	Fluoranthene	10.0	382	111		202.3
16	Pyrene	8.5	393	156		202.3
17	Benzofluorenes	2.0	413	189-190		216.3
18	Chrysene	3.0	448	255-256		228.3

¹Values from Handbook of Chemistry and Physics, 1971-72, 52nd ed., Chemical Rubber Publishing Co., Cleveland, Ohio.